510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k042795

B. Purpose for Submission:

New Device

C. Measurand:

Glucose and Blood Pressure

D. Type of Test:

Glucose - Quantitative Amperometric (Glucose Oxidase)

Blood Pressure - Non-invasive Oscillimetric

E. Applicant:

TaiDoc Technology Corporation

F. Proprietary and Established Names:

Taidoc Clever Chek TD-3213 Blood Glucose and Blood Pressure Measurement System

G. Regulatory Information:

1. Regulation sections:

21 CFR § 862.1345, Glucose Test System

21 CFR § 862.1660, Quality Control Material, Assayed and Unassayed

21 CFR § 870.1130, Noninvasive blood pressure measurement system.

2. Classification:

Class II (Glucose Test System)
Class I -reserved (Quality Control Material)
Class II (Blood Pressure Measurement System)

3. Product code:

NBW, CGA (Glucose Test System)
JJX (Quality Control Material)
DXN (Blood Pressure Measurement System)

4. Panel:

75 (Clinical Chemistry) - Glucose Test System and Quality Control Material
74 (Cardiovascular) - Blood Pressure Measurement System

H. Intended Use:

1. Intended use/ Indications for Use:

The Clever Chek TD-3213 Blood Glucose and Blood Pressure Measurement System is intended for in vitro diagnostic use. The system is intended to be used for the quantitative measurement of capillary whole blood from the fingertip. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The system is also intended to be used to measure non-invasively the systolic and diastolic blood pressure and pulse rate of an adult individual, over age 16, at home by using a technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to 5.25 inches to ~ 7.75 inches.

2 Special conditions for use statement(s):

This device is not intended to diagnose or screen for diabetes mellitus, and is not to be used on neonates. For in vitro diagnostic use only.

3. Special instrument requirements:

Not applicable

I. Device Description:

This device combines the functions of a blood glucose meter and a blood pressure measurement system in one unit. Supplied with the meter are the test strips, code strip, lancets, lancet holder, storage case, and control solutions. To measure blood glucose, the user inserts the code strip that is included with each bottle of test strips. A numerical code appears in the display when the code strip is inserted. Once the user confirms that the numerical code on the display, code strip, and strip bottle all match, a test strip is inserted into the meter and glucose testing can proceed. The sponsor has provided instructions and illustrations explaining that the blood drop will be pulled into the strip sample entry by capillary action and that the confirmation window must be completely filled with blood to get an accurate result. Results are stored in the meter's memory for tracking purposes. The lancet supplied with this device was previously cleared under k833344. The two control solutions supplied with this device were previously cleared under k041107.

To measure blood pressure, the user is instructed to wrap the cuff around the wrist approximately ¼ to ½ inch below the ball of the thumb. Users should sit or lie down for 5 - 10 minutes before taking a reading, and are instructed not to move or talk during the measurement. The sponsor has also provided instructions and illustrations explaining that the user must be sitting and the blood pressure cuff must be at the same level as the user's heart to obtain an accurate reading. Results are stored in the meter's memory for tracking purposes.

Blood glucose and blood pressure cannot be measured simultaneously. The device's software will produce an error code if this is attempted.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bayer Diagnostics Glucometer Elite Diabetes Care System

   APM Blood Pressure Monitoring System, BP108A

2. Predicate 510(k) number(s):

   k020208

   k0401593. Comparison with predicate:

Similarities - Glucose Meter		
Item	Device	Predicate
Specimen	Same	Capillary Whole Blood
Methodology	Same	Electrochemical, Glucose Oxidase
Measuring Range	Same	20 - 600 mg/dL
Display	Same	Direct Readout; no calculation required
Strip Coding	Same	Required

Differences - Glucose Meter		
Item	Device	Predicate
Alternate Site Testing	Specimen may be taken from fingertip only	Can be used for sites other than finger
Power Source	Two 1.5 V AAA batteries	Two 3V batteries
Number of Readings Stored in Memory	352	20

Similarities - Blood Pressure Monitoring System		
Item	Device	Predicate
Type of Reading	Same	Non-invasive, diastolic and systolic blood pressure, pulse rate
Location of Reading	Same	Wrist
Cuff Circumference	Same	5.25 - 7.75 inches
Stethoscope	Not Required	Not Required
Power Source	Same	Two 1.5 V AAA batteries

Differences - Blood Pressure Monitoring System		
Item	Device	Predicate
Measuring Range	30 - 280 mm Hg	20 - 280 mm Hg
Pulse Rate	40 - 199 beats / min	40 - 200 beats / min
Number of Readings Stored in Memory	352	128

K. Standard/Guidance Document Referenced (if applicable): see C.1.9

NCCLS EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline

NCCLS EP6-P; Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Proposed Guideline

NCCLS EP7-P; Interference Testing in Clinical Chemistry; Proposed Guideline

IEC 61000-4-2 / 1995; Electromagnetic Compatibility (EMC) - Part 4-2: Testing and Measurement Techniques - Electrostatic Discharge Immunity Test-Edition 1.2; Edition 1:1995 Consolidated with Amendments 1:1998 and 2:2000

IEC 61000-4-3 / 2002; Electromagnetic Compatibility (EMC) - Part 4-3: Testing and Measurement Techniques - Radiated, Radio-Frequency, Electromagnetic Field Immunity Test-Edition 2.1; Edition 2:2002 Consolidated with Amendment 1:2002

EN 60601-1:1990; Medical electrical equipment - Part 1: general requirements for safety including amendments A1, A2, A11, A12, and A13

EN 61010-1-2 / 2001; Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: general requirements

EN 61326; Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements-Includes Amendment A1: 1998 and A2:2001; IEC 61326:1997 + A1:1998 + A2:2000

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 1998

L. Test Principle:

Glucose: the glucose oxidase in the strip reacts with the glucose in the sample to produce an electrical current proportional to the glucose concentration. The meter measures the current and converts it to the corresponding glucose concentration in mg/dL or mmol/L.

Blood pressure: the pressure sensor in the cuff detects small changes in pressure and converts them to electrical signals. The meter analyzes the signals and converts them to standard measurements of pulse rate and systolic and diastolic blood pressure.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility of the glucose meter:

   The sponsor evaluated precision of the device by using venous whole blood samples spiked with glucose (for within-day precision) and glucose control solutions (for day-to-day precision).

   The venous whole blood samples had concentrations of approximately 44, 99, and 143, 228, and 325 mg/dL. The protocol was conducted at three different sites and testing for each concentration, which consisted of 20 measurements, was completed within 30 minutes to minimize the effects of glycolysis. The results for the venous whole blood samples were as follows:

Within-day precision				
		Site 1	Site 2	Site 3
Sample 1 (mg/dL)	mean	44.0	44.3	43.9
	SD	1.5	1.7	1.4
	CV*	3.3%	3.8%	3.1%
Sample 2 (mg/dL)	mean	99.4	100.5	99.1
	SD	3.0	2.8	2.3
	CV	3.0%	2.8%	2.3%
Sample 3 (mg/dL)	mean	142.7	134.8	141.7
	SD	4.1	5.0	4.3
	CV	2.9%	3.7%	3.0%
Sample 4 (mg/dL)	mean	227.5	228.5	226.0
	SD	7.0	7.9	7.6
	CV	3.1%	3.4%	3.4%
Sample 5 (mg/dL)	mean	325.1	324.4	326.5
	SD	8.1	8.0	8.2
	CV	2.5%	2.5%	2.5%

*Coefficient of variation = (total imprecision SD/mean) X 100

The glucose control solutions had concentrations of approximately 70, 128, and 315 mg/dL. The protocol was conducted at three sites using two meters. For each concentration, four measurements were taken over 20 days. The results for the control solutions were as follows:

Day-to-day precision				
		site 1	site 2	site 3
Control solution 1 (mg/dL)	mean	69.7	70.0	69.5
	SD	2.5	2.2	2.1
	CV*	3.6%	3.2%	3.1%
Control solution 2 (mg/dL)	mean	127.6	127.2	126.5
	SD	2.8	3.9	2.8
	CV	2.2%	3.1%	2.2%
Control solution 3 (mg/dL)	mean	314.9	314.2	320.6
	SD	8.5	9.8	9.6
	CV	2.7%	3.1%	3.0%

*Coefficient of variation = (total imprecision SD/mean) X 100

b. Linearity/assay reportable range:

The linearity of the glucose measurements was demonstrated by comparing eleven prepared whole blood samples on the Taidoc meter and a glucose reference method. The eleven samples ranged in concentration from a low of approximately 20 mg/dL to a high of approximately 560 mg/dL. Linear regression of the comparison data yielded the following relationship:

Taidoc = (1.07 X Reference Method) + 13 mg/dL
$r^2 = 0.9985$

The reportable range of glucose measurements is 20 - 600 mg/dL

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The controls supplied with this device were previously cleared under k041107. The sponsor has shown traceability of the Taidoc glucose meter to a laboratory analyzer.

d. Detection limit:
20 mg/dL

e. Analytical specificity:

Specificity of the glucose meter was assessed by spiking various endogenous and exogenous compounds into prepared whole blood samples. The sponsor first prepared a low whole blood control at approximately 80 mg/dL glucose and a high whole blood control at approximately 300 mg/dL glucose and confirmed these concentrations prior to the addition of the interferents. The sponsor then added increasing amounts of potential interferents to both control solutions and again measured the glucose using the Taidoc meter. If the change in glucose measurement from the control solution was less than 10%, this was considered no interference. Results of this testing were as follows:

Interferent	Highest Concentration Where No Interference Seen
Acetaminophen	Low Control - 5 mg/dL High Control - 5 mg/dL
Ascorbic Acid	Low Control - 1.25 mg/dL High Control - 3 mg/dL
Dopamine	Low Control - 2 mg/dL High Control - 2 mg/dL
L-dopa	Low Control - 3 mg/dL High Control - 3 mg/dL
Methyldopa	Low Control - 0.5 mg/dL High Control - 0.75 mg/dL
Tolbutamide	Low Control - 200 mg/dL High Control - 200 mg/dL
Uric Acid	Low Control - 10 mg/dL High Control - 10 mg/dL
Triglycerides	Low Control - 2000 mg/dL High Control - 2000 mg/dL

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

   a. *Method comparison with predicate device:*

      The sponsor performed a consumer study to demonstrate that the glucose meter can be used properly by consumers with the directions provided. This study included 40 paired whole blood and plasma samples at three different sites, for a total of 120 comparisons and 120 consumers. Each site compared the Taidoc meter to a different laboratory analyzer. Results were as follows:

      Site 1
      Taidoc = (0.9952 X laboratory analyzer) + 2 mg/dL
      $r^2 = 0.9734$

      Site 2
      Taidoc = (0.9812 X laboratory analyzer) + 4 mg/dL
      $r^2 = 0.9728$

      Site 3
      Taidoc = (0.8647 X laboratory analyzer) + 15 mg/dL
      $r^2 = 0.9575$

   b. *Matrix comparison:*
      Not Applicable. The glucose meter is intended to be used with capillary whole blood from the finger only.

3. Clinical studies:

   a. *Clinical Sensitivity:*

      Not Applicable.

   b. *Clinical specificity:*

      Not Applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:**

   Not Applicable.

5. Expected values/Reference range:

   The sponsor has included in their labeling a fasting reference range of 70-100 mg/dL (3.9-6.1 mmol/L)

N. Instrument Name:

Taidoc Clever Chek TD-3213 Blood Glucose and Blood Pressure Measurement System

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional readings. There are no disposable components used to measure blood pressure.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from the finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

   A Code Strip is provided with each batch of test strips to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing a high and low glucose control solution with this device. When a test strip is inserted into the meter and the M (Memory) button is pressed, "CtL" is displayed and the control mode is activated. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Note: the following comments are based on a Division of Cardiovascular Device consult review, and apply to the blood pressure portion of this device only.

The device is said to be in compliance with EN 60601-1, General Requirements for Safety. The manufacturer also indicates that the device was tested and met requirements of EN 60601-1-2 for EMC.

The manufacturer has provided software validation test protocols and results of testing which indicate how well the software handled problems such as cuff overpressure, pressure transducer failure, too long to inflate (indicating a leaking hose, etc.), and other mechanical problems. Also, they have provided reliability testing to 10,000 cycles as well as tables indicating applicable conformance to the ANSI/AAMI SP10 standard.

Comparison to Predicate

Both the Taidoc device and the predicate use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. A wrist cuff is inflated automatically. The manufacturer's device appears to differ from the predicate device in the tolerance for the pulse rate at +/- 1% cuff. The tolerance, for both devices, falls within what is called for in the ANSI/AAMI SP10 standard.

Software

The 510(k) submission contains a description of the software, labeling and system error messages related to software hazard testing plans and test results, software requirement specifications, software design specifications, and information about development. Also, the manufacturer has provided a software analysis that includes the result documents, approval test results, product testing description, and a hazard analysis. The software report was prepared in accordance with the FDA guidance document "Guide for the Content of Premarket Submission for Software Contained in Medical Devices."

Biocompatibility

The manufacturer has provided a signed statement that indicates that the arm/wrists cuffs, have been previously supplied under four different previously cleared 510(k)s – K020897, K012310, K021225, and K012796. Also, it is indicated that they are manufactured in the same manner (as the ones related to this device). Therefore, no statement appears to be necessary regarding the International Organization for Standardization document ISO 10993: Biological Evaluation of Medical Devices for biocompatibility testing (cuffs).

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.